

PRESS RELEASE

26th July, 2025 Vadodara, India

Alembic Pharmaceuticals Limited announces USFDA Final Approval for Carbamazepine Extended-Release Tablets USP, 100 mg, 200 mg, and 400 mg.

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Carbamazepine Extended-Release Tablets USP, 100 mg, 200 mg, and 400 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Tegretol-XR Extended-Release Tablets, 100 mg, 200 mg, and 400 mg, of Novartis Pharmaceuticals Corporation.

Carbamazepine Extended-Release Tablets are indicated for use as an anticonvulsant drug and also for the treatment of the pain associated with true trigeminal neuralgia. Refer label for a detailed indication.

Carbamazepine Extended-Release Tablets USP, 100 mg, 200 mg, and 400 mg, have an estimated market size of US\$ 71 million for twelve months ending March 2025 according to IQVIA.

Alembic has a cumulative total of 225 ANDA approvals (202 final approvals and 23 tentative approvals) from USFDA.

About Alembic Pharmaceuticals Limited

Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, has been at the forefront of healthcare since 1907. Headquartered in India, Alembic is a publicly listed company that manufactures and markets generic pharmaceutical products all over the world. Alembic's state of the art research and manufacturing facilities are approved by regulatory authorities of many developed countries including the USFDA. Alembic is one of the leaders in branded generics in India. Alembic's brands, marketed through a field force of over 5500 are well recognized by doctors and patients.

Information about the Company can be found at www.alembicpharmaceuticals.com; (Reuters:ALEM.NS) (Bloomberg:ALPM) (NSE:APLLTD) (BSE:533573)

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